

R E M A R K S

Reconsideration of the rejection and allowance of the amended and new claims are respectfully requested.

Claim 14 as amended is not anticipated by Meyer Patent No. 4,178,638 on the basis that the slots 44' qualify as depressions.

Claim 14 has been amended to more particularly recite features which differentiate the heart valves of the application from those described in the Meyer '638 Patent. The heart valves described in the application are totally different in concept from those described in the Meyer patent.

Claim 14, as amended, describes the leaflets as being supported by pairs of guides in opposed elongated depressions. As a result, the major arcuate edges of the leaflets swing downstream during opening. The leaflets in Meyer, on the other hand, are hinged from single locations at the midpoints of their major arcuate edges. As a result, the adjacent minor edges 49 of the leaflets in the Meyer heart valves swing downstream as the leaflets open.

Applicant believes that the heart valves according to the present invention operate in a superior manner to those described in Meyer. The elongated depressions of the heart valves described in the application provide for washing of the depressions and guides by flowing blood. In contrast, the slots 44' in Meyer represent a restricted area where blood is likely to stagnate, and the weep holes 63 would be ineffective to overcome this deficiency. In addition, regions downstream of the pivots in the Meyer valves are at all times shielded by

the leaflets from forward flowing blood and thus, represent additional regions where stagnation and subsequent clotting may occur.

Claim 14, as amended, calls for shifting axes of the leaflets. In the Meyer valves, the pivotal axes are essentially fixed.

With the added limitations, Claim 14 cannot now be said to be anticipated by the Meyer '638 Patent. This also applies to added Claim 19.

It is further submitted that amended Claim 14 would not be obvious from any combination of Bokros Patent No. 4,178,639 or 4,254,508 in view of Meyer Patent No. 3,589,392 or '638. Although the leaflets of the present invention, like the leaflets described in the Meyer patents, are sections of tubes, the operation of the heart valves of the present invention is quite different from that described in the Meyer patents, and also, from the heart valves described in the Bokros patents.

The guides and depressions, as described in Claim 14, operate to shift the eccentric pivotal axes downstream as the leaflets pivot to the open position. As the axes shift downstream, the guides slide against the depressions scraping away any blood which may have begun to stagnate on the surfaces of the guides and depressions. This continual cleaning of the guide and depression surfaces helps to assure that clotting will not occur in the regions of the guides and depressions. In this regard also, the downstream shifting of the axes exposes all surfaces of the depressions to flowing blood at some time during each opening and closing cycle, thereby

preventing stagnation within the depressions. No such downstream displacement occurs in the heart valves described in the Bokros patents, which, like the heart valves described in the Meyer Patents, have essentially fixed pivotal axes. In the Bokros '639 Patent, the guides rotate within hemispheric depressions, and the pivotal axes extend generally between the centers of the opposed depressions. In the Bokros '508 patent, the pivotal axes extend generally between the apices of pie-shaped depressions. In each case, the pivotal axes remain substantially stationary during opening and closing of the leaflets.

Claim 14 furthermore calls for stop means which are positioned downstream of the pivotal axes. In the '639 Bokros Patent, the leaflets stop in their open position with upstream portions abutting side surfaces 47 which are located upstream of the pivotal axes. In the Bokros '508 patent, the leaflets stop in their open position either with the guides in contact with upstream edges 46 of depressions or with the leaflets in contact with stopping surfaces 74 disposed upstream of the pivotal axes. The downstream location of the stops creates a more central region of contact with the leaflets. Because the references cited by the Examiner do not show the recited features, Claim 14 is now believed to be allowable.

Claim 19 has been added to particularly claim additional features embodied in the heart valves shown in FIGURES 15 and 18 of the application. These additional features are not present in the heart valves of the references applied against Claim 14. In addition to reciting the feature

of shifting eccentric axes, a feature not shown in the Bokros or Meyer patents, Claim 19 calls for depressions each having a straight edge along which elongated guides lie in the closed position, a straight edge along which the guides lie in the open position and an arcuate edge along which downstream ends of the guides travel as the leaflets pivot from the closed to the open position. The arcuate edges are located farther from a plane through the centerline of the passageway than are the pivotal axes, and thus the configuration of guides and depressions recited in Claim 19 is different from those shown in the cited prior art.

The interengagement arrangement recited in Claim 19 is totally different than that shown and described in the Meyer patents. In the '639 Bokros patent, the depressions are hemispherical and have no straight edges along which the guides lie in either the open or closed position.

Although there are similarities between the depression-guide arrangement shown and described in the Bokros '505 patent and the depression-guide arrangement recited in Claim 19, there are significant differences in function as well as design. The depressions in the '508 Bokros Patent have arcuate edges which are located closer to the centerline of the passageway than the pivotal axes, and ends of the guides move upstream along the arcuate edges as the leaflets pivot to the open position. As a consequence of the depressions of the FIGURE 15 and 18 embodiments being orientated differently within the valve body than the depressions in the Bokros heart valve, the pivotal axes of the FIGURE 15 and 18 embodiments are

located closely adjacent the minor edges of the leaflets whereas the pivotal axes of the leaflets in the Bokros heart valve are more centrally located. As a result, the pivotal axes in the FIGURE 15 and 18 heart valves are located further from the centers of gravity of the leaflets than are those in the Bokros heart valve. The further the pivotal axes are from the center of gravity the greater the moment of force which will act upon the leaflets to open and close the leaflets. Thus the differences between the depression-guide arrangements in the Bokros '508 Patent and the depression-guide arrangements shown in FIGURES 15 and 18 are not merely of design, but provide for improved functioning of these heart valves.

The features recited in Claim 19 are not shown by the cited references, either individually or combined, and Claim 19 is believed to be allowable.

Claim 1-13 and 16-18 were allowed. In view of the foregoing remarks, it is believed that Claims 14 and 19 are allowable. In the absence of more pertinent prior art, it is believed that the application is now in condition for allowance, and favorable action is respectfully requested.

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Respectfully submitted,

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